K092666

## 510(k) Summary Of Safety And Effectiveness

**Summary Date** August 28, 2009

**Submitter Name and Address**

Boston Scientific Corporation
47900 Bayside Parkway
Fremont, CA. 94538

SEP 30 2009

**Contact Person:**

Jim Leathley
Regulatory Affairs Project Manager
Phone: 510 440 7836
Fax: 510 440 7752
Email: leathlej@bsci.com

**Trade Name:** InZone™ Detachment System and IZDS™ Connecting Cable

**Common Name:** Power Supply and Connecting Cable

**Classification Name:** The InZone Detachment System is intended for use with all Boston Scientific Detachable Coils in the embolization of intracranial aneurysms and other vascular malformations of the neuro and peripheral vasculature.

Boston Scientific's detachable coils are class II devices (special controls) classed as vascular and neurovascular embolization devices under 21 CFR 870.3300 (KRD) and 21 CFR 882.5950 (HCG), respectively.

The special control for the devices is FDA's guidance document, *Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices* (issued 29 Dec 2004).

**Legally Marketed Predicate Devices:**

| Reference (Clearance Date) | Device |
|---|---|
| K021494 (6 June 2002) | GDC® Power Supply and Detachable Coil Connecting Cables |

## 510(k) Summary Of Safety And Effectiveness (cont.)

**Device Description:**

Boston Scientific's InZone™ Detachment System is a sterile, handheld, single-patient use device designed for use with Boston Scientific Detachable Coils. The device consists of an enclosure with a detachment button, five LED indicator lamps, a funnel inset at its distal end, and a cable connection port. The device comes pre-loaded with two AAAA (1.5 VDC) batteries.

Boston Scientific's IZDS™ Connecting Cable is a 180 cm cable intended for use with the InZone Detachment System in the detachment of Boston Scientific's GDC® Detachable Coils and Matrix2® Detachable Coils. The cable completes the connection between the InZone unit and a patient return electrode (a 20 or 22 gauge uncoated stainless-steel hypodermic needle) inserted subcutaneously at the patient's groin.

**Accessories:**

There are no accessories to the InZone Detachment System or IZDS Connecting Cable.

**Indications for Use / Intended Use:**

The InZone Detachment System is intended for use with all Boston Scientific Detachable Coils in the embolization of intracranial aneurysms and other vascular malformations of the neuro and peripheral vasculature.

**Comparison to Predicate Device:**

Boston Scientific Corporation's InZone Detachment System has the same intended use and indications for use as the current legally marketed predicate device, Boston Scientific's Detachable Coil Power Supply cleared under premarket notification K021494 (cleared 6 June 2002).

Although the InZone Detachment System incorporates modifications in materials, firmware, packaging, and instructions for use, the modifications do not alter the fundamental scientific technology of the predicate device. The following is a brief overview of the modifications in comparison to the predicate device:

The materials and components of the InZone unit consist of polymers, screws, resistors, capacitors and other electronic components. Components are similar to those used in the construction of the predicate device. Verification testing has demonstrated the InZone device to be substantially equivalent to the current legally marketed predicate device.

**Comparison to Predicate Device (cont.):**

The firmware of the InZone™ Detachment System is similar to that used in the operation and control of the predicate device. A level of concern assessment has determined the InZone firmware to be the same level of concern as for the predicate device. Verification testing has demonstrated the InZone device to be substantially equivalent to the current legally marketed predicate device.

Packaging modifications have been made to accommodate the different size of the InZone unit as well as the fact that the device is to be provided as a sterile unit. Verification testing, including validation of the sterilization process, has demonstrated the InZone device to be substantially equivalent to the current legally marketed predicate device.

Intended use and indications for use are the same as for the predicate device. Revisions to the directions for use reflect procedural differences in using the sterile, hand-held InZone Detachment System within the sterile field.

Boston Scientific's IZDS™ Connecting Cable has the same intended use as the current legally marketed predicate device, the black / ground connecting cable from Boston Scientific's Connecting Cable set cleared under K021494. The modifications that have been made that have resulted in the IZDS Connecting Cable do not alter the fundamental scientific technology of the predicate connecting cable.

Risk assessment of the modifications, in the form of design and use failure modes and effects analysis (design and use FMEAs), has been conducted in accordance with EN ISO 14971 +A1:2003. Boston Scientific has determined the modifications to the predicate device raise no new questions of safety or effectiveness.

Verification testing of the InZone Detachment System and IZDS Connecting Cable, including electrical safety testing in accordance with applicable parts of the EN 60601-series of standards, has demonstrated the devices to be substantially equivalent to the predicate device.

## 510(k) Summary Of Safety And Effectiveness (cont.)

**Conclusion:**

Since the subject modifications do not alter the intended use/ indications for use of the predicate devices or the fundamental scientific technology of the predicate devices; and because risk assessment of the modifications and successful verification testing raise no new questions of safety and effectiveness, Boston Scientific has determined the InZone™ Detachment System and IZDS™ Connecting Cable to be substantially equivalent to the current legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Boston Scientific Corporation
c/o James Leathley
Regulatory Affairs Project Manager
47900 Bayside Parkway
Fremont, CA 94538

SEP 30 2009

Re: K092666
Trade Name: InZone™ Detachment System and IZDS™ Connecting Cable
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG
Dated: August 28, 2009
Received: August 31, 2009

Dear Mr. Leathley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological and
Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K092666

**Special 510(K), Boston Scientific Corporation – InZone™ Detachment System and IZDS™ Connecting Cable**

Boston Scientific

**INDICATIONS FOR USE STATEMENT**

510(k) Number: K092666

**Device Name:** InZone™ Detachment System

**Indications for Use:**

Boston Scientific's InZone™ Detachment System is intended for use with all versions of BSC Detachable Coils in the embolization of intracranial aneurysms and other vascular malformations of the neuro and peripheral vasculature.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

**Prescription Use** Yes
**(Per 21 CFR 801.109)**

Jeff Toy
(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K092666